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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/760,091	01/16/2004	Thomas L. Cantor	532212000624	2110

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MORRISON & FOERSTER LLP
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EXAMINER

CHEU, CHANGHWA J

ART UNIT	PAPER NUMBER
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1641

MAIL DATE	DELIVERY MODE
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12/13/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/760,091	Applicant(s) CANTOR ET AL.	
	Examiner Jacob Cheu	Art Unit 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 September 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 47-71, 78-84, 86, 92, 93 and 95-107 is/are pending in the application.
- 4a) Of the above claim(s) 47-68 and 98-107 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 69-71, 78-84, 86, 92 and 95-97 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8/29/07, 10/19/07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's amendment filed on 9/25/2007 has been received and entered into record and considered.

The following information provided in the amendment affects the instant application:

A. Claims 1-46, 72-77, 85, 87-91, 94 had been cancelled.

B. Currently, claims 69, 71, 78-84, 86, 92-93, 95-97 are under examination. Claims 47-68 and 98-107 are withdrawn from further consideration.

Claim Rejections - 35 USC § 112

New Matter

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. The rejections of claims 69, 71, 78-84, 86, 92-93, 95-97 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement are maintained. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

"three-dimensional epitope"

It is noted that the instant claim recites "an antibody binds to a bioactive, three-dimensional epitope of a parathyroid hormone (PTH), wherein said isolated antibody binds to said three-dimensional epitope within a whole PTH with a higher affinity than its binding to said three-dimensional epitope within a PTH fragment". No support from the

specification can be found. Although applicant in the Remarks indicates the inherent characteristics of the antibody, particularly at page 8, line 24-25 and Figure 11, however no "three-dimensional" epitope PTH fragment was ever discussed in the whole specification (See Remarks page 13, fourth paragraph).

Furthermore, applicant also submitted Dr. Lerner's binding analysis in support of the assertion with respect to the newly amended claims. Supra. (See Exhibit B). However, in view of the experimental conducted by Dr. Lerner, particularly #plate 2 in Exhibit 3, the binding activity of the whole PTH is even smaller than PTH fragment (1-34) and (37-82) (See rows B, C and F and column 11). This is contradictory to what Dr. Lerner described in the affidavit (See page 5 to page 6, particular page 6, second paragraph).

Examiner also found no definition of the three dimensional epitope is discussed in the specification. In the art, the term "three dimensional epitope" generally refers to a nonlinear discontinuous epitope. It is also called "conformation epitope" (See Moreau et al. Bioinformatics 2006 Vol. 22, page 1088-1095; Regenmortel et al. Methods in Enzymology 1996 Vol. 9, page 465-472). Regenmortel et al. describe that the three dimensional epitope is composed of several fragments scattered along the protein sequence and brought together in spatial proximity where the protein is folded (See Moreau et al., page 1088, right column; also See Regenmortel et al. page 468, Figure 1, model A). This is essentially similar to what applicant described in the Remarks (See page 13, second paragraph- *"because the conformational or three dimensional epitopes are formed from two or more stretches of polypeptide that are distant from one another in the primary structure, this means that the conformational or the three dimensional epitopes are better formed when the entire protein is in its natural conformation (e.g. folding)"*). Based upon such definition, the claim language of "said three-dimensional epitope within a PTH *fragment*" cannot be true in the (1-9) PTH fragment since the 9 short amino acid residues peptide is a continuous *linear* peptide, not a three dimensional epitope (See affidavit Exhibit 3 data)(emphasis added).

It is also noted that applicant claims a genus where an antibody "binds to a three-dimensional epitope of a PTH, wherein said isolated antibody binds to said three-dimensional epitope within a whole PTH with a higher affinity than its binding to said three dimensional epitope *within a PTH fragment*" (emphasis added). Assuming *arguendo*, both the (1-9) and (1-34) fragments do inherently contain a three dimensional epitope as declared by Dr. Lerner, nevertheless no experimental data on further C-terminal PTH fragments, e.g. 1-38, 1-40, 1-60, 1-70 and 1-80, are presented. The two fragments, i.e. 1-9 and 1-34 merely represent 40% of the whole PTH (full length 1-84 in human, 1-86 in rat). Both species, at most, represent subgenus of the whole PTH. It has been held that a subgenus is not necessarily implicitly described by a genus encompassing it and a species upon which it reads. see *In re Smith*, 458 F.2d 1389, 1395, 173 USPQ 679, 683 (CCPA 1972). Taken together, the instant claims now recite a limitation which was not clearly disclosed in the specification and recited in the claims as originally filed.

Response to Applicant's Arguments

3. A terminal disclaimer with respect to applicant's US 6689566 issued patent had been acknowledged and approved.
4. The rejections of claims 69, 71, 78-84, 86, 92-93, 95-97 under 35 U.S.C. 112, first paragraph, new matter, are maintained (See above).

Conclusion

5. No claim is allowed.
6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacob Cheu whose telephone number is 571-272-0814. The examiner can normally be reached on 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jacob Cheu
Examiner
Art Unit 1641




LONG V. LE 12/06/07
SUPERVISORY PATENT EXAMINER
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